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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

WELLS, LAUREN Q

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 11/06/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Applicati n N .

09/782,520

Applicant(s)

LEREBOUR ET AL.

Examiner

Lauren Q Wells

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1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 13-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

Claims 13-24 are pending. The Amendment filed 8/29/03, Paper No. 15, amended claim 13.

Applicant's arguments with respect to claims 13-24 have been considered but are moot in view of the new ground(s) of rejection.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/29/03 has been entered.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In particular, the specification is not enabled for composition in the absence of antibiotic, bactericidal or fungicidal agents.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d

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1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

The invention is directed to a method of reducing the adhesion of microorganisms to the surface of the skin and/or mucous membranes in the absence of antibiotic, bactericidal or fungicidal agents, comprising containing to the skin and/or mucous membranes a composition comprising an effective quantity of at least one fatty substance free of carbohydrate units, having a melting point less than 35 C and an interfacial tension of between 6 and 27 mN/m.

(2) The state of the prior art

The prior art teaches compositions of the instant invention for application to the skin. Additionally, the prior art teaches an incredible number of chemically distinct antibiotic, bactericidal, and fungicidal agents, ranging from ethanol to complex organic cyclic compounds.

(3) The relative skill of those in the art

The relative skill of the those in the art is high.

(4) The predictability or unpredictability of the art

The unpredictability of the cosmetic art for decreasing microorganisms on the skin is very high. For example, microorganisms often cause acne. It is unpredictable how one active composition will be effective on one person with acne caused by microorganisms, but not effective on another person with acne caused by microorganisms. Thus, it is unpredictable how a given active ingredient will affect microorganisms on skin in a given population.

(5) The breadth of the claims

The claims are very broad. The active ingredient can be any fatty substance, so long as it has a melting point of less than 35 C and an interfacial tension between 6 and 27mN/m, wherein most fatty substances have these properties. Additionally, the breadth of the phrase "in the absence of antibiotic, bactericidal or fungicidal agents" is very broad. It includes an incredible number of compounds that are completely diverse in their chemical structure and activity. For example, ethanol is a two carbon chain with a hydroxyl group, and imidazolidinyl urea is a compound containing two nitrogen containing heterocycles attached by amide bonds.

(6) The amount of direction or guidance presented

While the specification provides direction and guidance as to what the fatty substances are, the specification provides no direction or guidance as to what the antibiotic, bactericidal or fungicidal agents are. Additionally, the specification contradicts itself, as it states that the method is in the absence of antibiotic bactericidal or fungicidal agents, yet the example on page 14-15 of the specification contain an antioxidant and a perfume, wherein both of these are

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bactericides. See US 6,528,042, which teaches compounds, such as flavonoids, as having both anti-oxidant activity and antimicrobial activity (Col. 4, lines 13-15). See also US 6,569,410, which teaches that numerous perfumes and essential oils have antimicrobial properties (Col. 11, lines 57-58). Thus, the specification provides no direction or guidance as to what compounds are excluded by the statement "in the absence of antibiotic, bactericidal or fungicidal agents", and what compounds are included.

(7) The presence or absence of working examples

As stated in the previous paragraph, while there is a working example, the working example contains ingredients that are considered bactericides. Thus, the working example does not support the claims.

(8) The quantity of experimentation necessary

In the instant case, an incredible amount of experimentation would be necessary to determine what antibiotic, bactericidal or fungicidal agents are excluded from the instant invention and what agents are not excluded, as antibiotic, bactericidal and fungicidal agents encompass an incredible number of chemical compounds with varying structures and activities.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 13-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Mougin et al. (5,851,517).

Mougin et al. exemplify a facial gel comprising 10g isopropyl palmitate, 5g petrolatum, 0.15g modified hectorite, 5g ozokerite, 5g oxyethylenated sorbitan sepaoleate, and 75g of a dispersion, wherein the dispersion comprises polymethyl acrylate in a volatile liquid paraffin.

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Thus, isopropyl palmitate comprises approximately 10% of the composition. It is respectfully pointed out that a facial gel is for application to the skin of the face. See Col. 11, lines 1-13; Col. 8, lines 28-37.

The claims are directed to a method of reducing the adhesion of microorganisms to the surface of the skin and/or mucus membranes, comprising contacting the skin with a composition comprising an effective quantity of a fatty substance free of carbohydrate units, having a melting point less than 35 C and having an interfacial tension of between 6 and 27 mN/m. Any properties exhibited by or benefits provided the composition are inherent and are not given patentable weight over the prior art. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties Applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not inherently possess the same properties as instantly claimed product. The prior art teaches application to the skin of compositions containing the same components as instantly claimed, which would inherently reduce the adhesion of microorganisms to the surface of the skin and/or mucous membranes, intending to combat comedones, dandruff, acne, mycosis, or body odor, as instantly claimed. Applicant has not provided any evidence of record to show that the prior art compositions do not exhibit the same properties as instantly claimed.

Claims 13-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Santor et al. (6,524,594).

Santor et al. exemplify a gel formulation comprising 79% of a gelled mineral oil and hydrogenated butylene/ethylene styrene copolymer and hydrogenated ethylene/propylene/styrene

copolymer, 5% laureth-3, 15% isopropyl palmitate, and 1% cocamidopropyl betaine. The compositions are exemplified for application to the skin. See Col. 15, lines 30-Col. 16, line 15.

The claims are directed to a method of reducing the adhesion of microorganisms to the surface of the skin and/or mucus membranes, comprising contacting the skin with a composition comprising an effective quantity of a fatty substance free of carbohydrate units, having a melting point less than 35 C and having an interfacial tension of between 6 and 27 mN/m. Any properties exhibited by or benefits provided the composition are inherent and are not given patentable weight over the prior art. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties Applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not inherently possess the same properties as instantly claimed product. The prior art teaches application to the skin of compositions containing the same components as instantly claimed, which would inherently reduce the adhesion of microorganisms to the surface of the skin and/or mucous membranes, intending to combat comedones, dandruff, acne, mycosis, or body odor, as instantly claimed. Applicant has not provided any evidence of record to show that the prior art compositions do not exhibit the same properties as instantly claimed.

### ***Conclusion***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-4:30), with alternate Mondays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw

  
THEODORE J. CRIARES  
PRIMARY EXAMINER  
GROUP 1200/610